

**REMARKS**

Claims 32-51 are pending in this application. By this Amendment, 1, 6, 7, 10-12, 20-28, and 31 have been canceled, and new claims 32-51 have been added. Support for new claims 32-51 is found in originally filed claims 1-24, for example, and in the specification on page 6, lines 23-28, and page 8, lines 28-29, for example. Support for the change in the concentration of 5-bromo-4-chloro-3-indolyl-N-acetyl- $\beta$ -D-glucosaminide in the specification and as recited in new claim 36 is found in the specification on page 8, lines 32-33, for example. No new matter has been added by this Amendment.

The courtesies extended to Applicant's representative by Examiner Navarro at the interview held July 15, 2004, are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below and constitute Applicant's record of the interview.

As discussed at the interview, the previous claims of record, i.e., claims 1, 6, 7, 10-12, 20-28, and 31, did not reflect all of the amendments made to the claims during prosecution of this application. Thus, Applicant has rewritten the claimed subject matter as new claims 32-48 to correct this clerical error and to put the claims into better format for allowance. In addition, claims 49-51 have been added to further define the process of claim 40.

Also, as discussed at the interview, to clarify the prosecution record, Applicant notes that the previous response was officially filed in the U.S. Patent and Trademark Office on October 31, 2003, and not on November 26, 2003, as recited on page 2 of the Office Action.

**I. Formal Matters**

**A. Rejection under 35 U.S.C. §112, second paragraph**

The Examiner rejected claims 11 and 12 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the subject matter regarded as the invention in view of their alleged improper dependency.

Although Applicant traverses the rejection with respect to claim 12, the rejected claims have been canceled, and thus the rejection is now moot. Moreover, at the interview of July 15, 2004, the Examiner stated that claim 12 should not have been rejected. Instead, in view of the fact that the claim was free of the prior art, it should have been objected to for depending upon a rejected base claim.

In view of the cancellation of claim 11, withdrawal of the rejection is respectfully requested.

**B. Rejection under 35 U.S.C. §102**

The Examiner rejected claims 1, 6, and 7 under 35 U.S.C. §102(b) as being anticipated by Mega et al. (*J. Biochem.* 71(1): 107-14 (1972)) ("Mega"). Applicant respectfully traverses the rejection as applied to canceled claims 1, 6, and 7 and as applied to corresponding new claims 32-34, respectively.

The Examiner stated that Mega discloses a composition comprising the enzyme N-acetyl- $\beta$ -glucosaminidase, acetamide, and N-acetylglucosamine. According to the Examiner, N-acetyl- $\beta$ -glucosaminidase is a chromogenic or fluorogenic substrate that can be hydrolyzed by a hexosaminidase and acetamide is a compound that selectively inhibits the hexosaminidase activity of *C. tropicalis*. Therefore, the Examiner concluded that Mega anticipates the medium of claims 1, 6, and 7.

In an anticipation rejection, the cited reference must teach each element set forth in the claims. In this case, the *culture medium* of claims 32-34 comprises the following

elements: (1) a chromogenic or fluorogenic *substrate* that can be hydrolyzed by an enzyme of the hexosaminidase family; and (2) an acetamide that selectively inhibits the hexosaminidase activity of *C. tropicalis*.

On the other hand, Mega discloses various *compositions* comprising:

1. (1) the *enzyme* N-acetyl- $\beta$ -D-glucosaminidase obtained from *Aspergillus oryzae*; and (2) a *substrate* of partially O-methylated N-acetyl-chitooligosaccharides, i.e., N-acetylglucosamine, 3-O-methyl-N-acetylglucosamine, 6-O-methyl-N-acetylglucosamine and 3,6-di-O-methyl-N-acetylglucosamine (pages 109-110, bridging paragraph);
2. (1) the *enzyme* N-acetyl- $\beta$ -D-glucosaminidase obtained from *Aspergillus oryzae*; and (2) a glucosaminide *substrate* of Table II;
3. (1) the *enzyme* N-acetyl- $\beta$ -D-glucosaminidase obtained from *Aspergillus oryzae*; and (2) the *substrate* phenyl N-acetyl-6-O-methyl- $\beta$ -D-glucosaminide, phenyl N-acetyl-3-O- $\beta$ -D-glucosaminide or phenyl N-acetyl- $\beta$ -D-glucosaminide (Table III); and
4. (1) the *enzyme* N-acetyl- $\beta$ -D-glucosaminidase obtained from *Aspergillus oryzae*; (2) an acetamide-compound, i.e., acetamide, acetanilide, N-acetylglucosamine, N-acetylgalactosamine, N-formylglucosamine, N-propionylglucosamine, glucosamine, glucose, galactose, mannose, N-acetyl DL-alanine, phenyl N-acetyl- $\beta$ -glucosaminide or methyl N-acetyl- $\beta$ -glucosaminide; and (3) the *substrate* *p*-nitrophenyl N-acetyl- $\beta$ -D-glucosaminide (Table IV).

Only the fourth composition disclosed by Mega comprises an enzyme, substrate, and acetamide-compound. However, the substrate *p*-nitrophenyl N-acetyl- $\beta$ -D-glucosaminide is *not* a chromogenic or fluorogenic substrate. In fact, none of the substrates in the disclosed compositions is a chromogenic or fluorogenic substrate. Thus, Mega fails to teach at least this component of the claimed culture medium.

On page 3 of the Office Action, the Examiner stated that the enzyme N-acetyl- $\beta$ -glucosaminidase corresponds to the chromogenic or fluorogenic substrate that can be hydrolyzed by an enzyme of the hexosaminidase family as claimed. However, as noted during the interview, N-acetyl- $\beta$ -glucosaminidase is an enzyme, not a substrate, let alone, a chromogenic or fluorogenic substrate that can be hydrolyzed by an enzyme of the hexosaminidase family.

More specifically, N-acetyl- $\beta$ -glucosaminidase is a glycolytic enzyme, which is an enzyme that acts on its substrate by hydrolyzing a bond between a sugar and an aglycone, whereas chromogenic and fluorogenic substrates are the compounds upon which the hexosaminidase enzyme exerts its catalytic activity. Chromogenic substrates are compounds containing a chromophoric group, such that the compounds react with hydrolytic enzymes *under the formation of color*. *See, e.g.*, specification, page 8, lines 16-34. Fluorogenic substrates are compounds containing a fluorogenic group, such that the compounds react with hydrolytic enzymes *under the formation of fluorescence*. *See, e.g.*, specification, page 8, lines 16-37.

At the interview, the Examiner stated that, alternatively, N-acetylglucosamine could be acting as a substrate in the manner claimed. However, N-acetylglucosamine is not a hydrolyzable chromogenic or fluorogenic substrate as claimed. Moreover, Mega describes N-acetylglucosamine as an inhibitor of enzyme activity (Table IV), whereas in the claimed culture medium, N-acetylglucosamine may function as an activator of the hexosaminidase activity of *Candida albicans*. *See, e.g.*, claim 34.

Finally, the Examiner stated that although Mega does not describe the cultivation of *Candida*, its failure to do so is not relevant since Applicant's preamble merely describes an intended use, which does not carry any patentable weight. Applicant respectfully disagrees with the Examiner's statement. As stated in the MPEP, section 2111.02, a reference cited in

an anticipation rejection must be capable of performing the intended use as recited in the preamble. Mega fails to describe a culture medium used to culture any yeast, let alone a culture medium used to specifically identify and/or differentiate *Candida albicans* and *Candida tropicalis*. In light of Mega's sole disclosure of the characteristics of a single enzyme from a single fungus, *Aspergillus oryzae*, there is no indication that Mega discloses a culture medium capable of being used to specifically identify and/or differentiate *Candida albicans* and *Candida tropicalis*.

In view of Mega's failure to disclose the elements of the claimed culture medium, Applicant asserts that the reference does not anticipate claims 1, 6, and 7, or new claims 32-34, corresponding thereto, and withdrawal of the rejection is respectfully requested.

**II. Pending Claims 35-51 Define Patentable Subject Matter**

Applicant thanks the Examiner for the indication that claims 10, 12, 20-28, and 31 contain allowable subject matter. Since new claims 35-48 substantially correspond to canceled claims 10, 12, 20-28, and 31, Applicant asserts that new claims 35-48 also contain allowable subject matter.

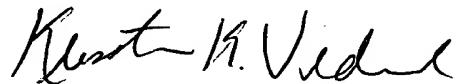
Furthermore, claims 49-51 further define the invention of claim 40. Thus, these claims are patentable for at least the same reasons as claim 40.

**III. Conclusion**

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 32-51 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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